

**Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review**

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

**§ 423.1968 Scope.**

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

[82 FR 5125, Jan. 17, 2017]

**§ 423.1970 Right to an ALJ hearing.**

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) *Calculating the amount in controversy in specific circumstances.* (1) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(2) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), CMS uses the projected value of the drugs subject to the drug management program to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills pre-

scribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017; 83 FR 16753, Apr. 16, 2018]